

REMARKS

Claims 1, 8, 17, and 21 are pending. Claims 2-7, 9-16, 18-20, 22, and 23 were cancelled without prejudice to Applicants' right to pursue the subject matter of those claims in a future continuation or divisional application.

Claims 8, 17 and 21 were previously presented. Claim 1 is currently amended. Support for the amendments can be found *inter alia* in the specification and specifically in the claims as originally filed. These amendments do not introduce new matter.

Priority

Applicants' Renewed Petition under 37 C.F.R. § 1.78(a)(6) filed on May 27, 2008, to accept unintentionally delayed claim under 35 U.S.C. § 119(e) for the benefit of the prior filed U.S. provisional application Serial No. 60/518,389 filed on November 6, 2003, was granted August 8, 2008. Applicants acknowledge with appreciation the grant of this Renewed Petition under 37 C.F.R. § 1.78(a)(6). Applicants have amended the specification to include a recitation to the priority claim.

Applicants submit that the requirements under 37 C.F.R. § 1.78(a)(4) have been met and that amendment to the specification including recitation to the priority claim satisfies the requirements of 37 C.F.R. § 1.78(a)(5). Applicants respectfully request that the Examiner grant the instant application the benefit of the earlier filing date.

Objections

The Examiner objected to the Supplemental Oath as reciting continuity to a provisional application for which the priority claim was denied. In view of the August 8, 2008 grant of Applicants' Renewed Petition under 37 C.F.R. § 1.78(a)(6), Applicants submit a Supplemental Declaration and Supplemental Data Sheet to reflect continuity to U.S. provisional application Serial No. 60/518,389 filed on November 6, 2003.

The Examiner objected to the amendment to the specification as inappropriate because Applicants' Petition pursuant to 37 C.F.R. § 1.78(a)(6) was dismissed. In view of the August 8, 2008 grant of Applicants' Renewed Petition under 37 C.F.R. § 1.78(a)(6), Applicants submit concurrently herewith an amendment to the specification which contains a reference to the prior filed U.S. provisional application Serial No. 60/518,389 filed on November 6, 2003. This amendment does not incorporate by reference the material of the prior filed provisional application.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 8, 17, and 21 are/remain rejected under 35 U.S.C. § 103(a) as unpatentable over Hollander (U.S. Pub. 2006/0105939) in view of an on-line NIH news alert ("The Use of Secretin to Treat Autism" Internet document dated 08/17/2001), and further in view of Swain (E. Swain, Pharmaceutical and Medical Packaging News (1999)) and PIERCE (PIERCE Technical Resource Sheet TR0043.0 "Protein Stability and Storage" 6/03). The Examiner takes the position that Hollander teaches treating autism with oxytocin, and discloses agents suitable for use in combination therapy. The Examiner also asserts that NIH News Alert teaches treating autism with secretin. The Examiner further asserts that (1) Swain teaches that packaging of pharmaceuticals can be beneficial; and (2) PIERCE teaches that protease inhibitors are added to protein solutions to lengthen shelf life.

In reply, applicants respectfully maintain the traversal of the rejection. The Examiner found the previously filed Declaration under 37 C.F.R. § 1.131. ineffective, because the Petition pursuant to 37 C.F.R. 1.78 (a)(6) was dismissed. In view of the August 8, 2008 grant of Applicants' Renewed Petition under 37 C.F.R. 1.78(a)(6), Applicants submit herewith a Declaration pursuant to 37 C.F.R. § 1.131 of the inventors Martha G. Welch, David A. Ruggiero, and Muhammad Anwar, declaring that the invention was conceived of prior to at least August 17, 2001. Accompanying the Declaration under 37 C.F.R. § 1.131 is Exhibit A, which is a redacted copy of relevant laboratory notebook pages. The Hollander reference was filed as a U.S. national phase application of a PCT application filed on October 3, 2003. The instant application claims priority to a U.S. provisional application Serial No. 60/518,389, which was filed on November 6, 2003. The Hollander reference

can therefore be removed as prior art based on the Declaration under 37 C.F.R. § 1.131. Without the Hollander reference, the remaining three references cited by the Examiner do not teach or suggest the claimed invention.

Applicants maintain their previous position that the NIH alert discloses only a single dose of secretin. The NIH alert states “Although secretin is generally considered safe for single dose diagnostic use, no data are available yet as to the safety of repeated doses over time and no data have been submitted on its safety and efficacy for children.” This discloses a single dose use, but there is no information on repeated doses, and no information on the use in children. The alert does not provide any reasonable expectation of success that secretin will work with repeated doses, in children, and let alone that a combination of secretin and oxytocin will have a synergistic effect to treat autism.

The Examiner asserts that in the specification there is no evidence of synergy of the combination of oxytocin and secretin. Without conceding the correctness of the Examiner’s positions Applicants have amended claim 1 to delete the term “synergistic.” Support for this amendment is found in the claims as filed.

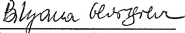
In view of the foregoing comments and amendments Applicants respectfully request withdrawal of all rejections.

In view of the above amendments and remarks, applicant believes the pending application is in condition for allowance.

Please charge our Deposit Account No. 08-0219, under Order No. 0019240.00477US2 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: October 13, 2003


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